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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,186	12/20/2001	Francis Lee	LD0251NP	9673

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EXAMINER	
WANG, SHENGJUN	
ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 05/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/027,186	FRANCIS LEE
	Examiner Shengjun Wang	Art Unit 1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 11 January 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-4,7,8,14,15,22-24,37 and 38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-4,7,8,22,23 and 37 is/are rejected.
- 7) Claim(s) 14,15,24 and 38 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 11, 2005 has been entered.

Claim Objections

2. Claims 14, 15, 24 and 38 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections 35 U.S.C. 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 7, 8, 22-23, ~~27~~, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Pettit (US 5,561,122, of record), and Bradley et al. (US 5,919,815), and in further view of Kerbel

The Pettit patent teaches combretastatin A-4 and its derivatives are known to be useful as antineoplastic agents, and are useful for the 'treatment of one or more neoplastic diseases, such as malignant melanoma, breast carcinoma, ovarian carcinoma, etc. See particularly, col. 6, lines 1-

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66. Bradley et al. teaches that taxol and its derivative are well-known in the art for anticancer utilities. See, particularly, columns 1-2.

The above reference and patent do not teach expressly the combination together.

However, one skilled in this art would find ample motivation from the prior art supra to combine the well known anticancer agents together where the results obtained thereby are no more than the additive effects of the anticancer agents; particularly since the above prior art teaches the ingredient for treating the same cancer systems. It is *prima facie* obvious to combine two compositions each of which is taught in the prior art to be useful for same purpose in order to form third composition that is to be used for very the same purpose; idea of combining them flows logically from their having been individually taught in prior art; thus, the claimed invention which is a combination of two known anticancer agents sets forth *prima facie* obvious subject matter. See In re Kerkhoven, 205 USPQ 1069. It is noted that the Pettit patent issued claim 2 is directed to treating "cells afflicted with a neoplastic disease" broadly. It is further noted that the instant elected combination is directed to well-known anticancer agents. Further, note the optimization of a result effective parameter, e.g., the schedule of administering the therapeutical agents, is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215.

Further, Bradley et al. further suggest the combination of taxol and its derivative to be used in combination with other known anticancer agents, since "the use of cocktails in treatment of cancer is routine" in the art (col. 13, lines 31-42). Agiogenesis compounds, such as combretastatin A4 is particularly mentioned. Kerbel disclosed that combretastatin is a known antiangiogenic agent and is known to be useful as anticancer agents. Kerbel further disclosed that

it is known in the art that the efficacy of conventional cytotoxic drug can be improved by combination with an angiogenic inhibitor. See, page 510. Therefore, one of ordinary skill in the art would have been further motivated to combine combretastatin with other anticancer drugs.

Response to the Arguments

The declaration under 37 CFR 1.132 by Dr. Sally Hill, and the remarks submitted January 11, 2004 have been fully considered. The declaration is persuasive in establish the unexpected benefit residing in the elected combinations, i.e., CA4P and taxol. However, there is no reasonably expectation that such benefit would be extrapolated to other combretastatin compounds encompassed herein (see pages 9-10 of the specification). The claims must be commensurate in the scope with any evidence of unexpected results. See MPEP 716.02 (d). Therefore, claims read on other combretastatin compounds, or other anticancer agents herein are properly rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


SHENGJUN WANG
PRIMARY EXAMINER
Shengjun Wang
Primary Examiner
Art Unit 1617